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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/315,298	05/20/1999	CHING-LEOU TENG	ISIS-3510	6350

34138 7590 12/10/2003

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EXAMINER	
EPPS FORD, JANET L	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 12/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/315,298	TENG ET AL.	
	Examiner	Art Unit	
	Janet L. Epps-Ford, Ph.D.	1635	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 November 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1,4-7,10,12,13,15,17,19,20,80,84,85 and 87-96 for the reasons of record*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Continuation of 3. Applicant's reply has overcome the following rejection(s): The rejection of claims 87-96 over Nielson et al. However, the rejection would be repeated under 35 USC 102(a). Although Applicants argue that the reference does not disclose bile salts, contrary to Applicant's assertions, the polyoxyethylene sorbitan ester described on page 21, lines 23-27 of Nielson et al. is encompassed within Applicant's definition of bile salt set forth in the specification as filed, see page 15 that states that derivatives of bile salts are included within the meaning of the term.

Continuation of 5. does NOT place the application in condition for allowance because: : a) Applicant's arguments in response to the rejection of claims 1, 5-7, 10, 17, 19-20 and 87-96 over Kawai et al. have been fully considered, but are not persuasive. Applicants traverse the instant rejections on the grounds that the cited references do not disclose a composition comprising an emulsion and a bile salt and an antisense oligonucleotide. However, as stated in the prior Office Action, Kawai et al. discloses compositions comprising wherein an emulsifier is distributed in a fat emulsion, wherein the emulsifier is a phospholipid or a nonionic surface active agent, wherein said agent is polyoxyethylene-(20)-ether (POE; Kawai; page 17, paragraph [0015]). Absent evidence to the contrary, the POE agent used in the emulsion of Kawai et al. meet all the limitations of Applicant's claimed composition. See for example, page 15 of the specification as filed that provides "examples" of the bile salts contemplated by the claimed invention. In particular, note lines 12-15 which states that the bile salts of the invention includes naturally occurring bile salts and their synthetic derivatives. Moreover, Applicants argue that Kawai et al. does not disclose compositions in "dosage form," in which the components of the composition are uniformly distributed. It is noted that the specification as filed does not provide a special limited definition of the term "dosage form," therefore the term "dosage form" as recited in the instant claims is not limited to only those compostions in which the components are uniformly distributed. Applicant's arguments do not take the place of evidence that the compositions of Kawai et al. are not in "dosage form."

b) Applicant's arguments over the rejection of claims 1, 4-7, 15 and 84 under 35 USC § 102(e) over Hnatowich et al. have been fully considered but are not persuasive. Applicants traverse on the grounds that this reference does not disclose "bile salts." Absent evidence to the contrary, the pharmaceutical salts listed in Hnatowich et al., see col. 18, lines 50-67, are encompassed by Applicant's definition of "bile salt" as set forth in the specification as filed, in particular wherein said bile salts include synthetic derivatives.